

## REMARKS

Claims 1, 10 – 21 and 25 – 29 are now in the application. Claim 1 is amended and claims 25-27 are added to more fully capture inventive subject matter in view of amendment to claim 1. No additional fee is required for the added claims.

This application was the subject of an appeal. In response thereto the application has been withdrawn from appeal and the Examiner has, in the most recent Office Action, withdrawn the art rejection (under Section 103) of claim 1 and has presented a new basis for rejection of claim 1 under Section 102. Claim 1 is now rejected as anticipated by Becket (U.S. 5, 710,372).

As best understood, the Examiner continues to reject, and has not changed her argument or her basis for rejecting, claims 10 – 21 under Section 102 or under Section 103. The rejections are based on Boehringer or Kenjou alone or in combination with Toranto or Cole. The Examiner has provided in the most recent Office Action another response to applicant's argument. To expedite allowance claims 10 and 20 are amended, while claims 28 and 29 are added to further define subject matter distinct over the prior art.

In the following remarks applicant first requests the Examiner to reconsider the rejection of claim 1 in view of the amendment presented herein and then urges allowance of claims 25 – 27. The remarks initially refer to claim 1 as most recently examined (prior to the amendment presented herein). Following discussion of claims 1 and 25 – 27, applicant presents argument concerning allowance of claims 10, 20 and 28-29.

With respect to claim 1 as examined, the basis for anticipation by Becket includes a statement that the reference discloses “bringing a different sample from the same source into contact with a second of the unitary test devices ... said responses providing information about temporal changes ...” but this is not a correct characterization of the Becket reference.

Although the Office Action notes in Becket a disclosure of “monitoring .. [that] provides indications of changes ...” at col. 2, line 3 of Becket, this is not the same as the examined claim language:

“bringing a sample ... to induce a response ... in [a] ... first test device ...  
bringing a different sample to ... induce a response ... in [a] second test device ...

said responses providing information about temporal change in analyte concentration.”

That is, claim 1 (as examined) required provision of two responses (one from a first device and one from a second device) to provide information about a temporal change. The Becket reference does not at all disclose determining temporal changes by determining two responses. In fact, despite use of language such as “monitoring .. [that] provides indications of changes ...” at col. 2, line 3 of Becket, the Becket reference only discloses methods for measuring concentration of a constituent (as stated at col. 11, .lines 28-30). The methods disclosed by Becket require:

“comparing a constituent concentration color calibration scale to the solid state test device ...” [col. 13, lines 7-9.]

That is clearly different from applicant’s teaching for providing two responses, one from each of two unitary test devices. In fact, Becket provides

“a test kit [that] comprises a) a [single] solid state test device ... and b) a constituent concentration color calibration scale ... [which] calibration scale comprises or is derived from a plurality of solid state test devices which have been exposed to aqueous fluid compositions having known concentrations ... [see col. 15, line 55 to col. 16, line 10].”

Becket neither teaches nor suggests obtaining two different samples from a source to provide “information about temporal change in analyte concentration.” Moreover, Becket would not have any need to do so because Becket requires a calibration scale with which it is possible to monitor analyte levels, e.g., relative to a specification.

Despite these patentable distinctions, claim 1 has been amended to be even more express. The claimed method determines a

“change in a level of concentration [by] ...

bringing a first sample from the source into contact with a first of the unitary test devices at a first time to induce, at the first time, a visually observable response ...

and subsequently bringing a second and different sample from the same source into contact with a second of the unitary test devices at a second time to induce at the second time, a visually observable response ...

and comparing a visually observable response induced in the first test device ... with a visually observable response induced in the second test device ... to provide information about a change in the level of analyte concentration between the two times.”

Both with respect to claim 1 as examined and claim 1 as now amended, Applicant submits that there is no art of record which can be combined to meet the terms of the recited subject matter. Specifically, none of the deficiencies which required withdrawal of the earlier rejection of claim 1 (based on Boehringer/ Kenjyou/Toronto) are compensated for by introduction of Becket. Moreover, to sustain a rejection under Section 102 or under Section 103, the Examiner must identify in the prior art every feature presented in the claim. In this regard, Becket is deficient, among other reasons, for not disclosing different responses (e.g., from different samples) which provide information about temporal change in analyte concentration.

For all of the above reasons, claim 1 is in condition for allowance. Furthermore, claim 25 also presents novel and non-obvious subject matter. The method of claim 25 requires:

“providing ... test devices ... including a plurality of regions, each ... responsive ... to indicate presence of the analyte ... without being determinative of a numerical concentration of the analyte in the source ... and  
comparing a visually observable response induced in the first test device directly with a visually observable response induced in the second test device to provide information about a change in the level of analyte concentration without requiring determination of analyte concentration in the source on either occasion [Emphasis Added].”

Each of the newly added dependent claims 26-27 further defines novel and non-obvious subject matter as well.

With regard to the Examiner’s response to applicant’s arguments, as they concern claims 10 and 20, applicant respectfully submits the Examiner’s analysis of the prior art is truly in error for reasons fully explained in the appeal brief. Nonetheless, these claims are amended to further

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recite features which differ from the prior art. As per claim 20, different indications of presence of analyte in the first and second samples provide evidence as to whether there has been a change in analyte level subsequent to providing the first sample. Claims 28 and 29 are added to clarify that the claims from which they depend are not so limited in scope.

The Examiner is requested to fully review applicant's argument concerning claims 10 and 20. If the Examiner still disagrees, the Examiner is requested to address all of the differences which applicant has noted to exist between the claim and the prior art.

For all of the above reasons and based on the amendments presented herein, the application is in condition for allowance.

Respectfully submitted,

A handwritten signature in black ink, reading "Ferdinand M. Romano", is written over a horizontal line.

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